BAYCARE Institutional Review Board **POLICY/PROCEDURE**

TITLE: Phase I & Phase IV Studies	**POLICY NUMBER:** IRB-002
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ISSUED FOR: All BayCare **SPONSORED BY:** BayCare Institutional Review Board	**ORIGINAL ISSUE DATE:** 08/19 **REVISION DATE:** **REVIEW DATE:**
APPROVED BY: BayCare Health System (BCHS) Institutional Review Board (IRB)	

This policy is developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion warrants taking other actions.

PURPOSE:

To inform Clinical Investigators of the Institutional Review Board (IRB) submission process for Phase 1 & Phase IV studies.

This policy was developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion warrants taking other actions.

What is clinical research?

Clinical trials are conducted to collect data regarding the safety and efficacy of new drug and device development. There are several steps and stages of approval in the clinical trials process before a drug or device can be sold in the consumer market, if ever.

Drug and device testing begins with extensive laboratory research which can involve years of experiments in animals and human cells. If the initial laboratory research is successful, researches send the data to the Food and Drug Administration (FDA) for approval to continue research and testing in humans.

Once approved, human testing of experimental drugs and devices can begin and is typically conducted in four phases. Each phase is considered a separate trial and, after completion of a phase, investigators are required to submit their data for approval from the FDA before continuing to the next phase.

POLICY:

A. In this policy, we will address Phase 1 and Phase IV trials only.

1. **PHASE I** studies assess the safety of a drug or device. This initial phase of testing, which can take several months to complete**, usually** includes a small number of healthy volunteers (20 to 100), who are generally paid for participating in the study. The study is designed to determine the effects of the drug or device on humans including how it is absorbed, metabolized, and excreted. This phase also investigates the side effects that occur as dosage levels are increased. About 70% of experimental drugs pass this phase of testing.
2. **Phase 1 Device trials:** medical device trials are smaller patient only groups. Drug trials are testing for safety and tolerability along with pharmacokinetics; medical device trials are mainly checking for the safety and the performance of the device so therefore have a much more patient focused outcomes.
3. **PHASE IV** studies, often called Post Marketing Surveillance Trials, are conducted after a drug

or device has been approved for consumer sale. Pharmaceutical companies have several objectives at this stage: (1) to compare a drug with other drugs already in the market; (2) to monitor a drug's long-term effectiveness and impact on a patient's quality of life; and (3) to determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies. Phase IV studies can result in a drug or device being taken off the market or restrictions of use could be placed on the product depending on the findings in the study.

4. **Phase IV**: Studies or **trials** conducted after a medicine is marketed to provide additional details about the medicine's efficacy or safety profile.

PROCEDURE:

B. Central IRB and BayCare Health System (BCHS) IRB submissions for review.

I. Studies that **cannot** go to a central IRB are **Pilot studies or Phase 1** studies on drugs or devices that are sponsored or investigator initiated.

II. The BayCare IRB reserves the right to maintain oversight of these types of studies at all BayCare institutions. Studies of these magnitudes are precarious and/or taxing on departments that required to supports them. The entire department is affected, as they usually require in-depth training, knowledge, forbearance, and immediate resolution to unforeseen issues. These types of study management is best carried out by trained research staff and oversight of these studies are best organized and measured by the local IRB.

III. **Phase IV** studies that are usually trials conducted after a medicine is marketed to provide additional details about the medicine's efficacy or safety profile.

IV. Some Phase IV studies can be submitted to a Central IRB only if the drug or device is already integrated at BayCare as part of the Standard of Care.

V. If the drug or device is not an integrated part of the standard of care at BayCare and it requires approval from the BayCare department/committee for the drug/device to assume usability; then the drug or device study route of approval will be the local BayCare IRB.

VI. All avenues for clarification as to which IRB should be used should be regarded as early as the first contact for the drug/device pre-qualifying site agreement between the sponsor and the Principal investigator.

VII. If Administrative Review is completed without or pending the specification of which IRB (Central or BayCare) should be used, and the study is submitted to the BayCare IRB for processing; the study will go to the BayCare IRB for review.

VIII. All Phase IV studies going through BayCare or Central IRB should include a sub-investigator as part of the submission process.

IX. Investigators/Staff should report to the IRB office after every two subjects are enrolled on the protocol.

X. The IRB auditor will audit the study at every quarterly interval after enrollment of subjects on the protocol. The auditor will make a report will be made to the IRB board regarding the findings.

XI. A letter of acceptable compliance or a letter regarding unorthodox findings will be sent to the investigator with instructions as to what is expected with a timeframe of compliance expectations.

XII. The auditor will either re-inspect the study upon notification of compliance as instructed or will follow-up during the next scheduled audit.

C. Regulatory requirements

While sponsors of medical device trials are not required to submit an Investigational New Drug Application (IND, per 21 CFR Part 312), they are subject to 21 CFR Part 812, Investigational Device Exemptions. Notably, the Investigational Device Exemption (IDE) requires hands-on device training for investigator and site staff, in addition to protocol training, because the efficacy and safety of the device may be highly dependent upon physician technique.

D. SAFETY REPORTING

The safety reporting requirements for devices differ from those for drugs. **For drugs,** sponsors are only required to report serious adverse events (SAEs) that may reasonably be regarded as caused by, or likely caused by, the drug. **For devices**, manufacturers are required to report all SAEs, even if they are not directly related to the device or the procedure in which the device is used. This requirement applies not just to implantables, but also to **in vitro** devices and diagnostics which are not used directly by the patient. If a participant in an **in vitro** diagnostic trial experiences a health condition that is not related to the device, that condition must still be reported.

E. Requirements for Adverse Events (AE) or Serious Adverse Events (SAE) Reporting

Any drug or device study approved through a Central IRB that exhibits a SAE or in the case of a device trial SAE/AE should be reported to the BayCare IRB as part of our reporting requirements. BayCare IRB will maintain the review and follow-up of all AE/SAE outside of what is reportable to a Central IRB.

BCHS IRB Disclaimer:

All Skype presentation to the BayCare IRB should have audio and video clarity in order to be acceptable to the IRB. In the event the IRB deems the presentation inaudible, the presenter must represent at the next schedule IRB meeting or at a meeting at his/her convenience.